UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL
SAFETY AND POLLUTION
PREVENTION

MEMORANDUM

Date: August 24, 2018
Revised: October 4, 2018

Subject: Efficacy Review for Valhalla,
EPA Reg. No. 4822-594,
DP Barcode: #447465
E-Submission: #28935

From: Sophie Nguyen
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Regulatory Management Branch I
Antimicrobials Division (7510P)

Applicant: S.C. Johnson & Son, Inc.
1525 Howe Street
Racine WI 53403

Formulation from the Label:

Active Ingredient	% by wt.
Alkyl dimethyl benzyl ammonium chloride	0.096%
Octyl Decyl Dimethyl Ammonium Chloride	0.072%
Dioctyl Dimethyl Ammonium Chloride	0.036%
Didecyl Dimethyl Ammonium Chloride	0.036%
Other Ingredients	99.760%
Total	100.000%

Inert ingredient information may be entitled to confidential treatment

I. BACKGROUND

Product Descriptions (as packaged, as applied): Aerosol spray application

Submission Type: Label amendment

Currently Registered Efficacy Claim(s): Disinfectant (bactericide, virucide) and deodorizer for use on hard, non-porous surfaces.

Requested Action(s): The registrant is submitting an amendment to the product label to add four new fragrances. To support the addition of this alternate formulation, the company is providing confirmatory efficacy data. Given that the company did not provide confirmatory efficacy data to support sanitizer claims, they are removing all sanitizer claims from the product's label.

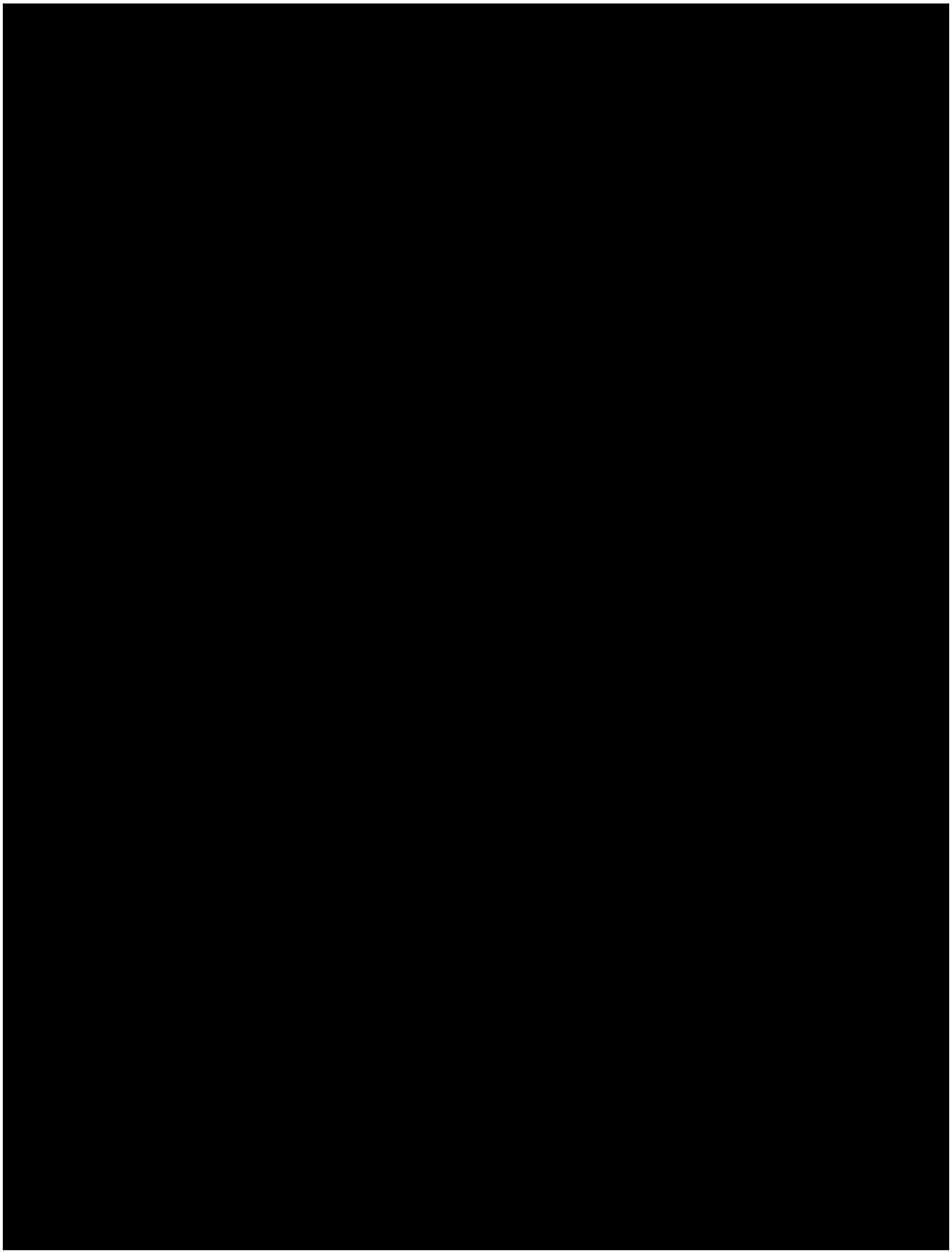
Documents considered in this review:

- Letter from the applicant to the Agency (dated May 2, 2018)
- Application for a Pesticide Amendment (Form 8570-1)
- Proposed Alternate Formulation CSF #18 (8570-4)
- Formulator's Exemption Form (8570-27)
- Certificate with Respect to Citation of Data (Form 8570-34)
- Data Matrices (Form 8570-35)
- Six efficacy studies (MRID #50557608 - 50557613); Statements of No Data Confidentiality Claims, Good Laboratory Practice Statement, and Quality Assurance Unit Summary are included in each study.
- Proposed label ver. ADR 04-30-2018

Efficacy Technical Screen and product background:
The submitted studies included Certificates of Analysis that captured the Quat concentrations at a higher percentage than the LCL. Six out of eight batches originally failed the screen.

The following justification was provided from the registrant in response to the technical screen deficiencies. After review and subsequent correspondence, it was determined that the justification for the adjusted concentration values was acceptable:

[redacted]



Inert ingredient information may be entitled to confidential treatment

II. USE DIRECTIONS

TO DISINFECT(‡)(^)(*) (AND DEODORIZE) (HARD, NON-POROUS SURFACES)**:**
Pre-Clean heavily soiled areas.
Spray 6-8 inches from hard non-porous surface(s) until thoroughly wet.
Let stand for 5 minutes.
((Then) (wipe.) ((Wipe with a wet cloth or sponge) (,) (then) (rinse (thoroughly) with water).)
(Rinse food contact surfaces with (clean) (or tap) (or potable) water).

III. AGENCY STANDARDS FOR PROPOSED CLAIMS

Disinfectants for Use in Hospital or Medical Environments; Confirmatory Efficacy Data Requirements:
Under certain circumstances, an applicant is permitted to rely on previously submitted efficacy data to support an application or amendment for registration of a product and to submit only minimal confirmatory efficacy data on the applicant's own product to demonstrate the ability to produce an effective formation. This includes a minor formulation change (e.g., a change in an inert ingredient) in a registered product. Confirmatory data must be developed on the applicant's own finished product. For hospital disinfectants, 10 carriers on each of 2 different batches of products (within the CSF) should be tested against *Staphylococcus aureus* (ATCC 6538) and *Pseudomonas aeruginosa* (ATCC 15442). For all the methods, the product should kill all the test microorganisms on all carriers. Control carrier counts specifications should be met. For a valid test, no contamination of any carrier is allowed.

Supplemental Claims:
An antimicrobial agent identified as a "one-step" disinfectant or as effective in the presence of organic soil must be tested for efficacy with an appropriate organic soil load, such as 5 percent serum. On a product label, the hard water tolerance level may differ with the level of antimicrobial activity (e.g., sanitizer vs. disinfectant) claimed. To establish efficacy in hard water, all microorganisms (i.e., bacteria, fungi, and viruses) claimed to be controlled must be tested by the appropriate Recommended Method at the same tolerance level.

IV. SYNOPSIS OF SUBMITTED EFFICACY STUDY

1.	MRID	50557608	Study Completion Date:	12/26/2017
Study Objective		Hard, non-porous surface disinfectant		
Study Title		AOAC Germicidal Spray Method		
Testing Lab, Lab Study ID		Accuratus Lab Services, Project No. A24192		
Test organism(s) ☐ 1 ☐ 2 ☒ 3 ☐ 4+		*Pseudomonas aeruginosa* (ATCC 15442) *Salmonella enterica* (ATCC 10708) *Staphylococcus aureus* (ATCC 6538)		
Test Method		Protocol No. JW01090617.GS.1 (*copy provided*)		
Application Method		Ready-to-use aerosol spray		
Test Substance Preparation	**Name/ID**	Gato-BMND-L 17306H65-1L GLP 941		
	Lots ☐ 1 ☒ 2 ☐ 3	Intermediate AI: Batch 941D4: 0.223% Quat Batch 941D5: 0.225% Quat Finished Good AI: Batch 941D4: 0.210% Quat Batch 941D5: 0.211% Quat		
	Preparation	Ready-to-use, as received from the Sponsor		
Soil load		5% FBS		
Carrier type, # per lot		Glass slides, 10 per batch		
Test conditions		**Contact time**	5 min.	**Temp** 20°C **RH** 45%
Neutralizer		20 mL Letheen broth with 0.07% Lecithin + 0.5% Tween 80		
Reviewer comments (i.e. protocol deviations and amendments, retesting, control failures, neutralizer, etc.)		Tested concentration: LCL Protocol Amendment: The test product application to the carriers is being revised from the number of sprays to duration of spay as the substance is in aerosol spray containers. Spraying time should be 2-3 seconds or until thoroughly wet. Additional Information: Additional testing associated with this test substance may be found in Accuratus Lab Services Project number: A24321		

2.	MRID	50557609	Study Completion Date:	12/19/2017
Study Objective		Hard, non-porous surface disinfectant		
Study Title		AOAC Germicidal Spray Method		
Testing Lab, Lab Study ID		Accuratus Lab Services, Project No. A24321		
Test organism(s) ☒ 1 ☐ 2 ☐ 3 ☐ 4+		*Staphylococcus aureus* (ATCC 6538)		
Test Method		Protocol No. JW01110217.GS.1 (*copy provided*)		
Application Method		Ready-to-use aerosol spray		
Test Substance Preparation	**Name/ID**	Gato-BMND-L 17306H65-1L GLP 941		
	Lots ☒ 1 ☐ 2 ☐ 3	Intermediate AI: Batch 941D5: 0.225% Quat Finished Good AI: Batch 941D5: 0.211% Quat		
	Preparation	Ready-to-use, as received from the Sponsor		

Soil load	5% FBS					
Carrier type, # per lot	Glass slides, 60 per batch					
Test conditions	**Contact time**	5 min.	**Temp**	20°C	**RH**	18%
Neutralizer	20 mL Letheen broth with 0.14% Lecithin + 1.0% Tween 80					
Reviewer comments (i.e. protocol deviations and amendments, retesting, control failures, neutralizer, etc.)	Tested concentration: LCL Additional Information: Additional testing associated with this test substance may be found in Accuratus Lab Services Project number A24192. Note: This batch was repeated for *S. aureus* under a different neutralizer and lower relative humidity.					

3.	**MRID**	50557610	**Study Completion Date:**	11/6/2017
Study Objective		Hard, non-porous surface disinfectant		
Study Title		AOAC Germicidal Spray Method		
Testing Lab, Lab Study ID		Accuratus Lab Services, Project No. A24243		
Test organism(s) ☐ 1 ☐ 2 ☒ 3 ☐ 4+		*Pseudomonas aeruginosa* (ATCC 15442) *Salmonella enterica* (ATCC 10708) *Staphylococcus aureus* (ATCC 6538)		
Test Method		Protocol No. JW01091817.GS.3 (*copy provided*)		
Application Method		Ready-to-use aerosol spray		
Test Substance Preparation	**Name/ID**	Gato BLAV-L 17306H65-4L GLP 944		
	Lots ☐ 1 ☒ 2 ☐ 3	Intermediate AI: Batch 944D4: 0.230% Quat Batch 944D5: 0.230% Quat Finished Good AI: Batch 944D4: 0.216% Quat Batch 944D5: 0.216% Quat		
	Preparation	Ready-to-use, as received from the Sponsor		
Soil load		5% FBS		
Carrier type, # per lot		Glass slides, 10 per batch		
Test conditions		**Contact time** 5 min.	**Temp** 20°C	**RH** 29%
Neutralizer		20 mL Letheen broth with 0.14% Lecithin + 1.0% Tween 80		
Reviewer comments (i.e. protocol deviations and amendments, retesting, control failures, neutralizer, etc.)		Tested concentration: LCL Protocol Amendment: Per sponsor request, this protocol is amended to update the spraying time from 2-3 trigger pulls to 2-3 seconds.		

4.	**MRID**	50557611	**Study Completion Date:**	12/20/2017
Study Objective		Hard, non-porous surface disinfectant		
Study Title		AOAC Germicidal Spray Method		
Testing Lab, Lab Study ID		Accuratus Lab Services, Project No. A24355		
Test organism(s) ☒ 1 ☐ 2 ☐ 3 ☐ 4+		*Salmonella enterica* (ATCC 10708)		
Test Method		Protocol No. JW01110217.GS.2 (*copy provided*)		
Application Method		Ready-to-use aerosol spray		

Test Substance Preparation	**Name/ID**	Gato BLAV-L 17306H65-4L GLP 944					
	Lots ☒ 1 ☐ 2 ☐ 3	Intermediate AI: Batch 944D5: 0.230% Quat Finished Good AI: Batch 944D5: 0.216% Quat					
	Preparation	Ready-to-use, as received from the Sponsor					
Soil load		5% FBS					
Carrier type, # per lot		Glass slides, 60 per batch					
Test conditions		**Contact time**	5 min.	**Temp**	20°C	**RH**	22%
Neutralizer		20 mL Letheen broth with 0.14% Lecithin + 1.0% Tween 80					
Reviewer comments (i.e. protocol deviations and amendments, retesting, control failures, neutralizer, etc.)		Tested concentration: LCL Protocol Deviation: The protocol states that the final test culture should be incubated for 48-54 hours prior to use. The final test culture used in this study was incubated for 56.3 hours. All controls and test results are valid.There is no impact on the overall intent of the protocol. Additional Information: Additional testing associated with this test substance may be found in Accuratus Lab Services Project number A24243. Note: This batch was repeated for *S. enterica* without changing the testing conditions.					

5.	**MRID**	50557612	**Study Completion Date:**	11/6/2017
Study Objective		Hard, non-porous surface disinfectant		
Study Title		AOAC Germicidal Spray Method		
Testing Lab, Lab Study ID		Accuratus Lab Services, Project No. A24242		
Test organism(s) ☐ 1 ☐ 2 ☒ 3 ☐ 4+		*Pseudomonas aeruginosa* (ATCC 15442) *Salmonella enterica* (ATCC 10708) *Staphylococcus aureus* (ATCC 6538)		
Test Method		Protocol No. JW01091817.GS.2 (*copy provided*)		
Application Method		Ready-to-use aerosol spray		
Test Substance Preparation	**Name/ID**	Gato BDD-L 17306H65-3L GLP 943		
	Lots ☐ 1 ☒ 2 ☐ 3	Intermediate AI: Batch 943D4: 0.235% Quat Batch 943D5: 0.235% Quat Finished Good AI: Batch 943D4: 0.221% Quat Batch 943D5: 0.221% Quat		
	Preparation	Ready-to-use, as received from the Sponsor		
Soil load		5% FBS		
Carrier type, # per lot		Glass slides, 10 per batch		
Test conditions		**Contact time** 5 min.	**Temp** 20°C	**RH** 28%
Neutralizer		20 mL Letheen broth with 0.14% Lecithin + 1.0% Tween 80		
Reviewer comments		Tested Concentration: > LCL		

(i.e. protocol deviations and amendments, retesting, control failures, neutralizer, etc.)	Protocol Amendment: Per sponsor request, this protocol is amended to update the spraying time from 2-3 trigger pulls to 2-3 seconds.

6.	**MRID**	50557613	**Study Completion Date:**	11/30/2017			
Study Objective		Hard, non-porous surface disinfectant					
Study Title		AOAC Germicidal Spray Method					
Testing Lab, Lab Study ID		Accuratus Lab Services, Project No. A24241					
Test organism(s) ☐ 1 ☐ 2 ☒ 3 ☐ 4+		*Pseudomonas aeruginosa* (ATCC 15442) *Salmonella enterica* (ATCC 10708) *Staphylococcus aureus* (ATCC 6538)					
Test Method		Protocol No. JW01091817.GS.1 (*copy provided*)					
Application Method		Ready-to-use aerosol spray					
Test Substance Preparation	**Name/ID**	Gato BLIN-L 17306H65-2L GLP 942					
	Lots ☐ 1 ☒ 2 ☐ 3	Intermediate AI: Batch 942D4: 0.234% Quat Batch 942D5: 0.235% Quat Finished Good AI: Batch 942D4: 0.220% Quat Batch 942D5: 0.221% Quat					
	Preparation	Ready-to-use, as received from the Sponsor					
Soil load		5% FBS					
Carrier type, # per lot		Glass slides, 10 per batch					
Test conditions		**Contact time**	5 min.	**Temp**	20°C	**RH**	34%
Neutralizer		20 mL Letheen broth with 0.14% Lecithin + 1.0% Tween 80					
Reviewer comments (i.e. protocol deviations and amendments, retesting, control failures, neutralizer, etc.)		Tested Concentration: > LCL Protocol Amendment: Per sponsor request, this protocol is amended to update the spraying time from 2-3 trigger pulls to 2-3 seconds. Test History: Testing of Batch 942D5 against Staphylococcus aureus resulted in no growth of the test organism in any of the 10 subcultures. One subculture demonstrated growth that was confirmed as a contaminant described in Table 5.					

V. RESULTS

Bactericidal Activity – Confirmatory Data - Mandarin					
Contact Time	**MRID Number**	**Organism**	**No. Carriers Exhibiting Growth/Total Carriers**		**Carrier Population (Average Log_{10} CFU/Carrier)**
			Batch 941D4	**Batch 941D5**	
RTU aerosol spray					
5 min.	50557608	*Pseudomonas aeruginosa* (ATCC 15442)	0/10	0/10	5.25

		Salmonella enterica (ATCC 10708)	0/10	0/10	4.73
		Staphylococcus aureus (ATCC 6538)	0/10	1/10	5.61
	50557609	*Staphylococcus aureus* (ATCC 6538)	--	1/60	5.69

Bactericidal Activity – Confirmatory Data – Lavender					
Contact Time	**MRID Number**	**Organism**	**No. Carriers Exhibiting Growth/Total Carriers**		**Carrier Population (Average Log$_{10}$ CFU/Carrier)**
			Batch 944D4	**Batch 944D5**	
RTU aerosol spray					
5 min.	50557610	*Pseudomonas aeruginosa* (ATCC 15442)	0/10	0/10	5.47
		Salmonella enterica (ATCC 10708)	0/10	3/10	4.51
		Staphylococcus aureus (ATCC 6538)	0/10	0/10	5.63
	50557611	*Salmonella enterica* (ATCC 10708)	--	0/60	4.63

Bactericidal Activity – Confirmatory Data – Citrus					
Contact Time	**MRID Number**	**Organism**	**No. Carriers Exhibiting Growth/Total Carriers**		**Carrier Population (Average Log$_{10}$ CFU/Carrier)**
			Batch 943D4	**Batch 943D5**	
RTU aerosol spray					
5 min.	50557612	*Pseudomonas aeruginosa* (ATCC 15442)	0/10	0/10	5.77
		Salmonella enterica (ATCC 10708)	0/10	0/10	4.62
		Staphylococcus aureus (ATCC 6538)	0/10	0/10	5.53

Bactericidal Activity – Confirmatory Data – Linen					
Contact Time	**MRID Number**	**Organism**	**No. Carriers Exhibiting Growth/Total Carriers**		**Carrier Population (Average Log$_{10}$ CFU/Carrier)**
			Batch 942D4	**Batch 942D5**	
RTU aerosol spray					
5 min.	50557613	*Pseudomonas aeruginosa* (ATCC 15442)	0/10	0/10	5.51

		Salmonella enterica (ATCC 10708)	0/10	0/10	4.74
		Staphylococcus aureus (ATCC 6538)	0(1)*/10	0/10	5.75

*Carriers showing growth which were confirmed as test organism were determined to be contaminants based on Gram stain and biochemical assay information confirming procedures reported in Table 5.

IV. CONCLUSION

MRID	Claim	Surface Type	Application Method(s) and Dilution	Contact Time	Soil load	Diluent	Organism(s)	Data support tested conditions?
50557608	Bactericidal activity (Mandarin)	Hard, non-porous surfaces	RTU aerosol spray	5 min.	5% FBS	--	*Pseudomonas aeruginosa* (ATCC 15442)	**Yes**
							Salmonella enterica (ATCC 10708)	**Yes**
							Staphylococcus aureus (ATCC 6538)	**No**
50557609 (batch repeat)	Bactericidal activity (Mandarin)	Hard, non-porous surfaces	RTU aerosol spray	5 min.	5% FBS	--	*Staphylococcus aureus* (ATCC 6538)	**No, Retesting is not permitted**
50557610	Bactericidal activity (Lavender)	Hard, non-porous surfaces	RTU aerosol spray	5 min.	5% FBS	--	*Pseudomonas aeruginosa* (ATCC 15442)	**Yes**
							Salmonella enterica (ATCC 10708)	**No**
							Staphylococcus aureus (ATCC 6538)	**Yes**
50557611 (batch repeat)	Bactericidal activity (Lavender)	Hard, non-porous surfaces	RTU aerosol spray	5 min.	5% FBS	--	*Salmonella enterica* (ATCC 10708)	**No, Retesting is not permitted**
50557612	Bactericidal activity (Citrus)	Hard, non-porous surfaces	RTU aerosol spray	5 min.	5% FBS	--	*Pseudomonas aeruginosa* (ATCC 15442)	**No**
							Salmonella enterica (ATCC 10708)	**No**
							Staphylococcus aureus (ATCC 6538)	**No**
50557613	Bactericidal activity (Linen)	Hard, non-	RTU aerosol spray	5 min.	5% FBS	--	*Pseudomonas aeruginosa* (ATCC 15442)	**No**

		porous surfaces					*Salmonella enterica* (ATCC 10708)	**No**
							Staphylococcus aureus (ATCC 6538)	**No**

V. LABEL RECOMMENDATIONS (label ver. ADR 04-30-2018)

1. The proposed label claims are acceptable regarding the use of the product, Valhalla (EPA Reg. No. 4822-594), as a ready to use aerosol spray disinfectant with the following fragrance against the following organisms on hard, nonporous surfaces for a 5-minute contact time:

   Fragrance- Lavender:
   Pseudomonas aeruginosa (ATCC 15442)
   Staphylococcus aureus (ATCC 6538)

   These claims are supported by the submitted data.

2. The proposed label claims are **not acceptable** regarding the use of the product, Valhalla (EPA Reg. No. 4822-594), as a ready to use aerosol spray disinfectant with the following fragrances against the following organisms on hard, nonporous surfaces for a 5-minute contact time:

   Fragrance- Mandarin:
   Pseudomonas aeruginosa (ATCC 15442)
   Staphylococcus aureus (ATCC 6538)
   Salmonella enterica (ATCC 10708)
   Retesting is not permitted for *S. aureus* under the tested conditions.

   Fragrance- Lavender:
   Salmonella enterica (ATCC 10708)
   Retesting is not permitted for *S. enterica* under the tested conditions.

   According to the email correspondence on 10/4/2018, retesting is permitted at this time for Mandarin and Lavender. Correspondence was as follows:
   "Fragrances – Mandarin and Lavender: Each of these fragrances had one failure on confirmatory data (10 carriers). Historically, it has been accepted that if 60 carriers are then run on the failed lot and passing results are obtained, the data would be acceptable to EPA. Failing data was only obtained on one batch for each of these fragrances, which has indication that it is not the formula. It is well known that qualitative methods (our only option at this time) show failures with no reasonable explanation. Therefore, these fragrances along with their associated claims should be acceptable.
   Efficacy's response: These fragrances and their associated claims are acceptable. Retesting in these situations is permitted at this time."

   Fragrance- Citrus:
   Pseudomonas aeruginosa (ATCC 15442)

Staphylococcus aureus (ATCC 6538)
Salmonella enterica (ATCC 10708)
The finished good active ingredient concentrations exceeded the LCL.

Fragrance- Linen:
Pseudomonas aeruginosa (ATCC 15442)
Staphylococcus aureus (ATCC 6538)
Salmonella enterica (ATCC 10708)
The finished good active ingredient concentrations exceeded the LCL.

These claims are not supported by the submitted data. Remove these fragrances and their respective organisms from the label. For the lavender fragrance, *Salmonella enterica* should not be listed on the label.

3. Throughout the label, when one-step claims are referenced in the same text as cleaning and sanitization and disinfection, a qualifier should be included such as "when use-directions for sanitization/disinfection are followed". See examples below:
    a. On page 6, "2 in 1 (One-Step) (All Purpose) (insert location – Table 3) (Antibacterial) (Disinfectant (&) (and) (Cleaner)" should be revised to add "when use-directions for disinfection are followed" without brackets. Please remove "All Purpose".
    b. On page 9, "One-step cleaner (and disinfectant)" should be revised to add "when use-directions for disinfection are followed".
    c. On page 2, "(Disinfectant) (Antibacterial†) (One Step) ((2 in 1) (Bathroom) (Kitchen) (All-Purpose) (&) (and) (cleaner)" should be revised to add "when use-directions for disinfection are followed". Remove "All-Purpose".
    d. "(This Product) is (a) (an) (Multi-)(Purpose) (Surface) (Task) (Antibacterial) (Bactericide) (Bactericidal) (Disinfectant) (Spray) (Disinfects) (Deodorizes) (Deodorizer) (One Step) (Virucide) (Virucidal) (Bathroom) (Kitchen) (Cleaner)" should be revised to add "when use-directions for disinfection are followed".

4. Throughout the label, remove brackets from "hard, nonporous" when describing surfaces. This descriptor is not optional. For example, the claim "For general (cleaning) of (hard) (non-porous) surfaces" should have brackets removed from "(hard) (non-porous)".

5. Throughout the label, the claims to disinfect "household surfaces", "entire home", and "all around" the home, bathroom, kitchen, etc. should be qualified to indicate "hard, nonporous surfaces".

6. Remove "All purpose" from the various claims under the section Marketing Efficacy Claims or revise to "multi-purpose".

7. Throughout the label, remove all claims for cold viruses. Product did not demonstrate effectiveness against at least two of the required organisms (Rhinovirus, Coronavirus, and Respiratory Syncytial Virus) to qualify for the claims.

According to the email correspondence between SCJ and the agency on 10/4/2018, cold virus claims may remain on the label:
"This formula is registered also under EPA Reg. No. 4822-607 which includes passing efficacy data on Human Coronavirus (see MRID #49407501). The reference to this MRID was inadvertently omitted from the Data Matrix in the original submission. We are taking the opportunity to correct this omission now and a revised Data Matrix is attached. Therefore, claims for cold viruses should be acceptable.
Efficacy's response: Claims against cold viruses are acceptable."

8. On page 2, under the directions for use for disinfection, revise "Pre-Clean heavily soiled areas" to "Pre-clean visibly soiled areas."

9. On page 6, remove or revise the claim "A (convenient) way to (clean up) (and) disinfect frequent messes." Messes can be cleaned but can't be disinfected. Similarly remove or revise the claim "Clean(s) (and) (disinfect)(s) (up) (small) spills like (toothpaste) (sink) (water marks) (misses) (drips) (on and around the toilet)."

10. On page 7, remove/revise the following claims:
    a. The claim "Disinfects the (hardest to reach) (dirtiest) places in your (bathroom) (kitchen) (home) (house)" should be qualified to indicate "hard, nonporous surfaces".
    b. Remove "(Disinfecting)" from "Fresh (Disinfecting) Scent of (insert fragrance – Table 5)." The claim is misleading because the scent/fragrance cannot disinfect surfaces.
    c. Remove "powerful" from the claim "From the brand(s) you trust to clean(,) (with a powerful disinfectant)" as this implies heightened efficacy.
    d. The claim "Help prevent the spread of (common) (household) viruses" should be revised to "Helps <u>reduce</u> the spread of (common) (household) viruses <u>on treated hard, nonporous surfaces.</u>"

11. On page 8 of the label, remove/revise the following claims:
    a. "Helps prevent cross-contamination of (hard) (nonporous) surfaces" should be revised to "Helps <u>reduce</u> cross-contamination <u>on treated</u> hard, nonporous surfaces." Brackets should be removed from "hard nonporous".
    b. Remove "(disinfects)" from the claim "(Improved) (scent) (fragrance name) (deodorizes) (disinfects) and leaves your (bathroom) (kitchen) (home) smelling fresh(!)(.)" The scent/fragrance is not disinfecting surfaces.
    c. Remove the ≥ signs from the claims to "Kills ≥99.9%..." This is misleading since data did not demonstrate such product performance.
    d. Remove "food-related bacteria" from the claim "Kills (household) (bacteria*) (viruses^) (odor-causing bacteria) (food-related bacteria) on hard, non-porous surfaces." The product did not demonstrate effectiveness against the representative organisms for food-contact surface sanitization to qualify for this claim.
    e. The term "disinfected" should be removed from the following claims. Alternatively, "disinfected" may be replaced with "clean":

i. "Leaves (hard) (non-porous) surfaces (disinfected) (and sparkling clean) (!)"
ii. "Leaves (hard,) (non-porous) surfaces disinfected"
iii. "Leaves (your) (kitchen) (home) (bathroom) (surfaces) (shiny) (clean) (and) (disinfected) (sanitary) (smelling clean)"
iv. "Leaves (insert location – Table 3) surfaces disinfected"

These claims imply residual disinfecting effect beyond the contact time.
According to the email correspondence between SCJ and the agency on 10/4/2018, the above claims may remain on the label:
"Residual claims must be linked to a time point (24 hours). The residual method that is required for residual claims has very specific wording that are allowed on a label. Therefore, since these claims do not indicate a time point, they should be acceptable. Also, we feel that removing these claims could place SCJ in a competitive disadvantage since there are other registered products that are similar in use and composition to Valhalla, which have been approved with these types of claims. For example, EPA Reg. No.'s 777-70, 5813-115, 67619-21, 6836-372, and 42182-9, to name a few.
Efficacy's response: These claims may remain on the label."

12. On page 9 of the label, remove/revise the following claims:
    a. "(Product name) (Helps prevent the spread of) (insert organisms - Section 5)" should be revised to "(Product name) (Helps reduce the spread of) (insert organisms - Section 5) on treated, hard, nonporous surfaces".
    b. Remove "Eradicates" from the claim "(Stops) (Kills) (Eliminates) (Eradicates) (germs‡) (microbes‡) (microorganisms‡) (bacteria*) (viruses^) where (they) (it) (live(s) (hide(s) (hide(s) out) (reside(s) (lurk(s) (lie(s) in wait) (where germs‡ are a concern)". The word implies heightened efficacy.
    c. Qualify "Virucide" and "Virucidal" from the claim "(This Product) is (a) (an) (Multi-)(Purpose) (Surface) (Task) (Antibacterial) (Bactericide) (Bactericidal) (Disinfectant) (Spray) (Disinfects) (Deodorizes) (Deodorizer) (One Step) (Virucide) (Virucidal) (Bathroom) (Kitchen) (Cleaner)".

13. On page 12 of the label, registrant should revise the claim "Helps prevent cross-contamination of treated (hard) (non-porous) surfaces" to "Helps reduce cross-contamination of treated hard non-porous surfaces." Remove brackets from the claim.

14. On page 17 of the label, registrant should specify "hard, nonporous" in the heading for ITEMS.

15. On page 19 of the label, registrant should specify the claim for "Toilets" by indicating above the water line or exterior of toilets.